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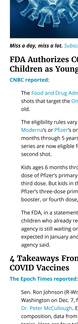
FDA Authorizes COVID Omicron Vaccines for Children as Young as 6 Months Old + More

The Defender's COVID Weeklies.It provides a roundup of the latest headlines related to the SARS CoV-2 virus, including its origins and COVID vaccines. The views expressed in the excerpts from other news sources do not necessarily reflect the views of The Defender.

By The Defender Staff



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FDA Authorizes COVID Omicron Vaccines for Children as Young as 6 Months Old

CNBC reported:

The Food and Drug Administration on Thursday authorized updated COVID shots that target the Omicron variant for children as young as 6 months old.

The eligibility rules vary depending on whether children received Moderna's or Pfizer's original vaccines as their primary series. Children 6 months through 5 years old who received Moderna's two-dose primary series are now eligible for an Omicron booster two months after their second shot.

Kids ages 6 months through 4 years old who have not yet received the third dose of Pfizer's primary series will now receive the Omicron shot as their third dose. But kids in the same age group who have already completed Pfizer's three-dose primary series cannot get the Omicron shot as a booster, or fourth dose, at this time.

The FDA, in a statement, said it did not authorize Omicron shots for those children who already received three doses of Pfizer's vaccine because the agency is still waiting on supporting data for those children. That data is expected in January and the FDA will review it as quickly as possible, the agency said.

4 Takeaways From Sen. Johnson's Panel on COVID Vaccines

The Epoch Times reported:

Sen. Ron Johnson (R-Wis.) held a panel on COVID-19 vaccines in Washington on Dec. 7, featuring experts including Dr. Robert Malone and Dr. Peter McCullough. Experts discussed vaccine development, vaccine complications, vaccine hesitancy and adverse event systems and other topics. Here are four takeaways from the panel.

Edward Dowd, a former BlackRock analyst now with the Humanity Project, showed data from the Society of Actuaries 2021 Group Life Insurance survey that showed a jump in excess mortality among young and middle-aged adults starting around the time the vaccines began being administered.

Several vaccines have been linked to side effects such as myocarditis, a form of heart inflammation that can turn deadly. Doctors testifying during the panel said they've seen an increase in patients with the inflammation. Dr. Kirk Milhoan, a pediatrician based in Hawaii, said he's seen more cases. The studies show that the spike protein, which the vaccines cause the body to make, is "cardiotoxic and cause the heart to be inflamed," Milhoan said. "Let that sink in, the current public health plan is asking our own body to make a cardiotoxin."

Dr. Harvey Risch, a professor emeritus of epidemiology at the Yale School of Public Health, presented data from the CDC that show young people face little risk from COVID-19.

McCullough, chief scientific officer of The Wellness Company, said that no randomized, double-blind, placebo-controlled trial has shown the vaccines reduce hospitalization or death. Such trials, known as RCTs, are generally considered the highest form of evidence for a drug.

French Health Authority Advises Against Use of Valneva's COVID Vaccine

Reuters reported:

France's Haute Autorite de Sante public health body advised the government not to use Valneva's (VLS:PA) VLA2001 COVID-19 vaccine as part of its wider vaccination strategy, although two small products should be included as booster shots. The snub caused Valneva's shares to fall, with Valneva down by around 1% during the late morning trading session in Paris.

The HAS body recommended Sanofi (SASY:PA) and GSK's (GSK.L) VidPrevtyn Beta and Novavax's (NVAX.O) Nuvaxovid shots to boost the vaccination of people who can not be given mRNA vaccines which shall remain the first choice, it said. "However, the HAS does not include the use of Valneva's VLA2001 vaccine in the current primary vaccination strategy", it added.

"There are no clinical efficacy or immunological data about the current variants. Therefore, it has not been retained for the time being," Elisabeth Bouvet, president of the HAS' vaccination department, told a news conference.

Experimental Decoy Drug Tricks Coronavirus, Then Destroys It

Los Angeles Times reported:

The coronavirus has been a shifty foe, with new variants and subvariants rapidly evolving to evade vaccines and treatments. Research at Boston's Dana-Farber Cancer Institute are working on an experimental drug that takes one of the virus' most dangerous traits — its talent for mutation — and turns it back on itself.

When the coronavirus binds to a specific type of receptor on the surface of a cell, it drives its spike protein in like a switchblade and initiates an infection.

The drug is designed to mimic that receptor, working like an assassin in an attractive disguise. When the coronavirus attempts to bind to it instead of to the real thing, it destroys the structure of the spike protein, permanently disabling the mechanism that would make that switchblade, according to a report published Wednesday in the journal Science Advances.

This approach backs the coronavirus into a corner: If it adopts a mutation that makes it bind less effectively with the decoy drug, it will also bind less effectively to the human cell.

DeSantis Pledges to Hold Vaccine Manufacturers 'Accountable'

The Epoch Times reported:

A comment made by Gov. Ron DeSantis during a private Republican Party of Florida event at the Florida Governor's Mansion has activists across the state abuzz with hope for the change they've been requesting for more than a year.

"We are going to work to hold these manufacturers accountable for this mRNA because they said there was no side effect. And we know that there have been. A lot," DeSantis said at the Dec. 3 event in Tallahassee.

"And so we did a study in Florida and we saw an 86% increase in [problems in] cardiac-related activity from people 18 to 39 from mRNA shots. And so we're going to be doing some stuff to try to hold them accountable."

Under the Public Readiness and Emergency Preparedness Act of the federal Emergency Use Authorization, the U.S. Health and Human Services (HHS) Secretary issued several declarations that provide liability immunity for activities related to medical countermeasures against COVID-19, as long as they did not commit fraud.

Walgreens Launches Free Paxlovid Delivery Service With DoorDash and Uber

ABC News reported:

Walgreens has launched a new delivery service for the COVID-19 oral antiviral therapy Paxlovid in partnership with DoorDash and Uber to get the treatment "directly to the doorsteps of those who need it."

Walgreens on Thursday said it has more than 8,000 locations offering same-day delivery services, available to anyone who lives within 15 miles of participating stores. Walgreens said that means real access to a lot of Americans — offering it to roughly 92% of the population.

Paxlovid, from Pfizer, is one of the few treatments still expected to hold up against currently circulating subvariants and comes as coronavirus hospitalizations are trending upward in the elderly.

To use Walgreens' new delivery service, eligible patients must have a Paxlovid prescription from a healthcare provider.

Wisconsin Youth Health Survey Shows Stress up Since COVID

Associated Press reported:

More than half of Wisconsin high school seniors surveyed in the fall of 2021 reported having significant problems with feeling very anxious, nervous, tense, scared or like something bad was going to happen, according to a health risk survey.

Rising numbers of students also reported symptoms of depression, self-harm and thoughts of suicide, according to the CDC's Youth Risk Behavior Survey released Tuesday.

The results are the first picture of Wisconsin students' mental health since the onset of the pandemic, the Milwaukee Journal Sentinel reported. The results were published by the Wisconsin Department of Public Instruction, which called for "drastic action."

The Youth Risk Behavior Survey goes out every two years to a sample of schools across the country selected to inform county, state and national reports, including 43 Wisconsin high schools. The national results have not yet been shared for 2021.

FDA Gives Priority Review to Pfizer RSV Vaccine for Older Adults

The Hill reported:

The Food and Drug Administration (FDA) accepted Pfizer's application for an RSV vaccine for older adults and is expected to issue an approval decision by the spring.

Pfizer in a statement on Wednesday said the FDA is going to review its application under the priority review program, which reduces the approval timeline by four months. The end of the review period is expected to be May 2023, Pfizer said.

In healthy adults and older children, RSV typically causes mild, cold-like symptoms that go away with moderate rest and self-care. But it can result in severe illness in infants and older adults.

There is no vaccine for RSV in either adults or children. If approved, Pfizer's candidate would become the first RSV vaccine for older adults.

WHO: COVID Disruption Resulted in 63,000 More Malaria Deaths

Associated Press reported:

The coronavirus pandemic interrupted efforts to control malaria, resulting in 63,000 additional deaths and 13 million more infections globally over two years, according to a report from the World Health Organization published Thursday.

Cases of the parasitic disease went up in 2020 and continued to climb in 2021, though at a slower pace, the U.N. health agency said Thursday. About 95% of the world's 247 million malaria infections and 619,000 deaths last year were in Africa.

"We were off track before the pandemic and the pandemic has now made things worse," said Abdisalan Noor, a senior official in WHO's malaria department.

Noor said he expected the wider rollout of the world's first authorized malaria vaccine next year to have a "considerable impact" on reducing the number of severe illnesses and deaths if enough children get immunized, adding that more than 20 countries have applied to vaccines alliance Gavi for help in securing the shot. Still, the vaccine is only about 30% effective and requires four doses.

Uganda Receives 1,200 Doses of Ebola Vaccine Candidates for Trials

Reuters reported:

A shipment of Ebola vaccine candidates to the east is used in a clinical trial has arrived in Uganda, where an outbreak has infected 142 people and killed at least 56, health authorities said on Thursday.

Last week Uganda said it had discharged its last Ebola patient from the hospital, raising hopes for the end of an outbreak of the deadly hemorrhagic fever declared on Sept. 20.

The WHO had said it would send three vaccine candidates to Uganda to be tested in a trial, one by the University of Oxford and Serum Institute of India, another by the Sabin Vaccine Institute and a third by Merck & Co Inc. (MRK.N).

At a ceremony to receive the vaccines in Entebbe, about 45 km (28 miles) south of the capital Kampala, Health Minister Jane Ruth Aceng said the 1,200 doses that had arrived were from the Sabin Institute.

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